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Newark / Philadelphia

November 15, 2024

VIA EMAIL & ECF
Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102

Re: ***U.S. ex rel. Silbersher v. Janssen Biotech Inc.***
Civil Action No. 19-12107 (MEF)(SDA)

Dear Judge Arpert:

Plaintiff-Relator Zachary Silbersher ("Relator") respectfully submits this letter in response to Defendants' November 13, 2024 letter (ECF No. 407). Defendants' reply is prohibited under L. R. 37.1(b)(3), without Your Honor's permission. It should be disregarded on this basis alone. Should Your Honor consider Defendants' reply, Relator requests the same consideration be granted to this letter.

Defendants claim they are addressing "factual inaccuracies," but that assertion itself is inaccurate and based on misleading statements. All three of Defendants' points lack merit.

First, Defendants say that Relator believes an "extension is appropriate." That is wrong. Relator previously offered a six-week extension as a matter of professional courtesy, *not* because Relator believes an extension is appropriate based on any of the circumstances raised by Defendants. (ECF No. 406, at 3)

Defendants also say that Relator "misrepresents" the time the Scheduling Order provided for the parties to serve expert reports (ECF No. 335). Again, that is wrong. The scheduling order provides Defendants with six months after fact discovery to serve their report, and two months for Relator—just as Relator has stated. (ECF No. 406, at 1)

Defendants wrongly suggest that they could not "meaningfully" have begun work on their own reports until they saw Relator's reports. But Relator's June 7, 2024 supplemental interrogatory responses mirrored much of Professor Tu's report. And Relator's oncology and medical expert, Dr. Ratain, provided his opinion in the underlying *inter partes* review of the relevant '438 Patent. He opined on many of the same issues that he includes in his report for this case. Defendants (then also represented by Sidley Austin LLP) deposed him on January 23, 2017, asking him questions about many of the same facts and data Dr. Ratain references in his current report. Defendants also previously served their own expert reports contesting many of these issues several times already (and have gone to trial with them), belying their arguments that they could not have begun work rebutting Dr. Ratain's opinion earlier.

Relator submitted reports from an FDA expert (Jon Clark) and a manufacturing expert (Dr. Robert Femia) opining on issues relating to generic entry. It has long been obvious these would be expert issues at trial. Moreover, Defendants knew, years before Relator filed his Complaint, the potential list of generic competitors, and Defendants had been modeling their FDA approval and entry dates in their internal analyses. Other issues, such as patent prosecution ethics or Patent Office policies and expectations concerning the duties of candor and good faith, are similarly obvious for these types of cases. Defendants' claim that they could not have begun work on their own expert reports months ago is not credible.

Second, Defendants repeat their argument that supposed deficiencies in Relator's expert reports hampered Defendants' ability to work on their own reports. They emphasize, for example, that Professor Tu disclosed "more than 40 new sources" (listed in ECF No. 408, Exhibit B) after his original report was served. This itself is inaccurate. These additional documents were provided only because Defendants insisted that Professor Tu disclose documents he merely screened for relevance, but which he did not believe that he "considered" in forming his opinion (such as irrelevant cases returned from terms and connectors legal searches), unless they were otherwise cited in the body of his report. (ECF No. 403, at 2) To avoid senseless motion practice, Relator simply chose to disclose them. (*Id*. 403, at 5) Defendants' suggestion that they could not begin meaningful work on a report regarding patent prosecution ethics and law (which is obviously a central issue at trial) because Professor Tu did not initially list these irrelevant references is baseless. Indeed, Professor Tu's report, including his opinions and the facts and data he relied upon in supporting them, has not changed at all.

Similarly, the "150 new documents"[1] (most of which were included in a supplemental disclosure and document production by Dr. Ratain on October 4, 2024, and added to the "References Considered in Forming Opinion" section of his updated report) were documents he believed were "not as pertinent" to his opinions as those he chose to cite in his report, but which he screened or "may have been subject to cursory review." Dr. Ratain added these documents because Relator wished to avoid pointless discovery motions that Defendants were insisting on filing. No changes were made to Dr. Ratain's opinions, or to the facts and data he relied upon in supporting them. (A redline of Dr. Ratain's supplemental report, Exhibit F of ECF No. 404, confirms that there were no such changes.)

Defendants also rehash their argument that they were not provided specific pin cites for certain references. In their moving papers, they cited only five examples from Dr. David Hyman's report and three in Dr. Robert Femia's report—out of hundreds of citations. (ECF No. 391, at 9). Relator has already explained why these citations were justifiable: they were string cites to general propositions, and often included articles that were only about a dozen pages long. (ECF No. 403, at 6) Defendants say that at least some of the sources were lengthy books. While

[1] It is unclear how Defendants arrived at this number—the documents added are listed in ECF No. 404, Exhibit F, at 2-3, and they include background documents such as the parties' filings, the decisions in the underlying cases, the parties' discovery responses, patent filings, and background documents produced by Defendants—nothing that Defendants did not already know.

Defendants do not identify any such sources, Dr. Femia listed a *Handbook on Pharmaceutical Chemicals* (ECF No. 404, at Exhibit C, 25). At Defendants' request, Dr. Femia provided the specific page numbers in the Handbook corresponding to the ingredients in Zytiga. But Defendants surely were not in the dark about which ingredients Dr. Femia consulted in the Handbook, even before Relator provided the pin cites, because the references concerned the ingredients in Zytiga, *Defendants' own drug*. It is also important to note that Relator has already provided pin cites to the citations that Defendants questioned—and offered to do so even before Defendants filed their motions.

Third, it was incumbent upon Defendants to seek an extension sooner. Defendants asked Relator for a four-month extension on October 25 at 4:00 pm. They asked for a response by 8:00 pm and filed their motion later that evening. Relator did respond at 6:34 pm by offering Defendants a six-week extension as a matter of professional courtesy to reach a pragmatic resolution. However, Defendants manufactured a dispute out of documents disregarded by the experts as irrelevant, publicly-available documents accessible *via* hyperlinks supplied by Relator, or a handful of pin cites, as excuses for delay.

Defendants also try to justify their discovery failures, including their choice not to take a single deposition before the fact discovery deadline, by trying to blame Relator and creating a false narrative about how discovery has been conducted in this case. Relator respectfully refers Your Honor to ECF No. 316, at 2-7 for proper context; those pages describe how *Defendants* withheld *basic*, critical information from Relator until fact discovery was about to end (such as who their patent attorneys spoke with prior to submitting the commercial success argument—and how Defendants' story fundamentally changed over the years from *zero* people outside of the legal department, to multiple people in the commercial group right when fact discovery was closing).[2] Relator overcame those discovery abuses and gamesmanship. In contrast, Defendants have no legitimate grievance about Relator's expert reports.

Respectfully,

/s/ Bruce D. Greenberg

Bruce D. Greenberg

BDG:emp

cc: All Counsel of Record (via ECF)

[2] This seismic—and last minute—change in Defendants' position concerning their diligence prior to making their commercial success argument (including a last-minute production of a trove of documents days before the critical deposition of their lead patent prosecution counsel), occurred at the heels of a Supreme Court decision calling into question their prior strategy relating to patent counsel's diligence, *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 751 (2023), as well as Judge Kiel's statements throwing water on Defendants' plans to flip privilege objections *after* the depositions of their witnesses (s*ee* ECF No. 326, at 23, lines 9-17).